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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,582	YANOFSKY, MARTIN F.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2004 and 07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *4-6,15-17 and 26-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-14,18-25 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/1/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-33 are pending.

2. Applicant's election with traverse of Group IV, claims 1-3, 7-14, 18-25, 29 and 30-33 to the extent they are directed to SEQ ID NO:12 in the reply filed on 7/12/2004 and 9/7/2004 is acknowledged. The traversal is on the ground(s) that according to the MPEP, where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. See the MPEP at 803.01.

This is not found persuasive because each sequence requires an independent search of USPTO databases and searching more than one sequence would be an undue burden on USPTO resources. The Office would like to point out to Applicants that MPEP 803.01 directs only Examiners with partial or full signatory authority to sign a restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-6, 15-17, and 26-28 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 1-3, 7-14, 18-25, and 29-33 including SEQ ID NO:12 are examined in the present office action.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 2-3, 7, 14, 18, 22, 25, 29, and 32 of this application.

Provisional application 60/104604 fails to disclose an AP1 regulatory element, or an AP1 regulatory element that has substantially the nucleotide sequence of *Arabidopsis* AP1 promoter of SEQ ID NO:12 or an active fragment thereof, or *Agrobacterium* rhizogenes. The effective filing date for claims 2, 7, 14, 18, 22, 25, 29, and 32 is 10/15/1999 and the effective filing date for claims 1, 3, 8-13, 19-21, 23-24, 30-31, and 33 is 10/16/1998.

Claim Objection

5. Claims 2, 14, 25, and 32 are objected to for being drawn to non-elected inventions.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 14, 18, 25, 29, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

Claims 2, 14, 18, 25, and 32 are indefinite in the recitation "AP1 regulatory element". Applicants define "AP1 regulatory element" to include orthologs of *Arabidopsis* AP1, which Applicants define as a MADS box gene product expressed, at least in part, in one or more floral organs of a plant and having homology to the amino acid sequence of *Arabidopsis* AP1 of SEQ ID NO:12. Applicants disclose SEQ ID NO:12 as the *Arabidopsis* AP1 promoter. It is unclear how a promoter sequence composed of DNA can have homology to an amino acid sequence (page 18, 1st full paragraph). Clarification is required.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3, 7-14, 18-25, and 29-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a transgenic plant, a method of producing a transgenic plant, an isolated nucleic acid molecule and a kit comprising a floral organ selective regulatory element, or wherein said regulatory element is an AP1 regulatory element, or wherein said AP1 regulatory element has substantially the nucleotide sequence of *Arabidopsis* AP1 promoter of SEQ ID NO:12 or an active fragment thereof, or wherein the isolated nucleic acid comprises at least 15 contiguous nucleotides of *Arabidopsis* AP1 promoter of SEQ ID NO:12. As discussed supra, "AP1 regulatory element" is indefinite. The office reads the phrase broadly to encompass any promoter sequence that expresses at least in part, in one or more floral organs of a plant. Applicants define "substantially the nucleotide sequence" as a floral organ selective regulatory element having nucleotide additions, deletions or substitutions relative to the AP1 promoter and retaining substantially the ability to confer selective expression in one or more floral organs (page 18, 2nd full paragraph).

Applicants disclose the *Arabidopsis* AP1 promoter of SEQ ID NO:12 in the sequence listing and in Figure 6a through 6f.

The Applicants do not identify essential regions of the AP1 promoter of SEQ ID NO:12, nor do Applicants describe any promoter sequence that is substantially the nucleotide sequence of *Arabidopsis* AP1 promoter of SEQ ID NO:12, or an active fragment thereof, or a nucleotide sequence comprising 15 contiguous nucleotides of SEQ ID NO:12 that has AP1 promoter activity.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences that have *Arabidopsis* AP1 promoter activity falling within the scope of the claimed genus of polynucleotides which encompass any nucleotide sequence that expresses in one or more floral

organs of a plant. Applicants only describe a single AP1 promoter sequence of SEQ ID NO:12. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the *Arabidopsis* AP1 promoter of SEQ ID NO:12, it remains unclear what features identify an AP1 promoter or a substantially the nucleotide sequence of an AP1 promoter. Since the genus of AP1 promoters has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

8. Claims 1-3, 7-14, 18-25, and 29-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising the entire 1.7 kb AP1 promoter of SEQ ID NO:12 plus the entire coding region of an AP1 including introns operably linked to a nucleic acid sequence encoding a cytotoxic gene product, and plant transformation therewith, to produce a transgenic plant characterized by suppressed flowering wherein suppressed flowering means that the flowers of the transgenic plant do not form, does not reasonably provide enablement for claims drawn to an isolated nucleic acid molecule comprising a floral organ selective regulatory element, or wherein the floral organ selective regulatory element is an AP1 regulatory element, or wherein said regulatory element comprises 15 contiguous nucleotides of SEQ ID NO:12, or wherein said AP1 regulatory element has substantially the nucleotide sequence of *Arabidopsis* AP1 promoter of SEQ ID NO:12, or an active fragment therewith, wherein said nucleic acid molecule is operably linked to a nucleic

acid molecule encoding a cytotoxic product and plant transformation therewith, or wherein a plant transformed with said nucleic acid molecule operably linked to a nucleic acid molecule encoding a cytotoxic product is capable of non-vegetative propagation, or a kit comprising said nucleic acid molecule operably linked to a nucleic acid molecule encoding a cytotoxic product. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a transgenic plant, a method of producing a transgenic plant, and an isolated nucleic acid molecule comprising a floral organ selective regulatory element, or wherein said regulatory element is an AP1 regulatory element, or wherein said AP1 regulatory element has substantially the nucleotide sequence of *Arabidopsis* AP1 promoter of SEQ ID NO:12 or an active fragment thereof. Applicants' claims are also drawn to a tissue of said transgenic plant capable of vegetative propagation. Because of the 112 2nd paragraph rejection of "AP1 regulatory element" as discussed above, the Office interprets "AP1 regulatory element"

as any promoter sequence that expresses at least in part, in one or more floral organs of a plant. Applicants define "substantially the nucleotide sequence" as a floral organ selective regulatory element having nucleotide additions, deletions or substitutions relative to the AP1 promoter and retaining substantially the ability to confer selective expression in one or more floral organs (page 18, 2nd full paragraph). Given this definition, the Office interprets "substantially the nucleotide sequence" to mean any sequence that directs expression in one or more floral organs. The office interprets "an active fragment thereof" to read on one base pair. Applicants broadly define "suppressed flowering" to mean that the transgenic plants produce flowers that are completely sterile or can be characterized by reduced fertility, although generally flowering is suppressed to the extent that the transgenic plant is completely sterile (page 7, 2nd paragraph).

The state-of-the-art teaches that non-coding nucleic acid sequences that exhibit base pair deletions, substitutions or rearrangements, cannot be expected to maintain their promoter or enhancer activity. Izawa et al (1993, J. Mol. Biol. 230 :1131-1144) teach the nucleotides flanking the G-box (CACGTC) and C-box (GACGTC) hexameric cores were shown to affect protein binding activity and specificity of bZIP transcription factors (page 1132, bottom of right column; page 1134, bottom of left column). Hao, et al (1998, The J. of Biological Chemistry 273 (41): 26857-26861) investigated the binding activities of ethylene-responsive element-binding proteins (EREBP) to their cis-element GCC box (AGCCGCC). Creating base-pair substitutions within the GCC box modulates binding specificity, implying that different positions within the GCC box are important for differential binding by different EREBP's, in particular, substituting T's for the two G's eliminates binding completely (*supra*, pages 26857, abstract and 26860, left column, 2nd paragraph).

Not only are DNA sequences located 5' to the translation start site (ATG) sensitive to base changes, but in some instances, intronic regions have been shown to be necessary for proper gene expression. Even though the present application does not claim intronic regions, this evidence is presented to demonstrate how a two base pair deletion or alteration of a cis-acting region can affect the binding of trans-acting factors that are important for proper spatial and temporal expression of a respective gene. Busch et al (1999, Science 285:585-587) and Lohmann et al (2001, Cell 105 :793-803) teach *LEAFY* (*LFY*) and *WUSCHEL* (*WUS*), which have been shown to be transcription factors that together activate proper *AGAMOUS* (*AG*) expression, do so by binding to the second intron of the *AG* gene. A two base-pair mutation within the binding site of either *LFY* or *WUS* eliminates binding of either *LFY* or *WUS*, respectively (Busch et al (supra) page 587 left column, 2nd paragraph; Lohmann et al (supra) page 799, bottom and top of left and right columns) and changes the temporal and spatial *AG* expression pattern.

Benfey et al (1990, Science 250:959-966) teach that the 35S CaMV promoter consists of domains that individually regulate spatial expression within plants. "The combination of each of the five B subdomains with domain A results in an expression pattern that differs from that of the individual subdomains or domain A" (page 961, left column, 2nd paragraph). In other words, deleting a required domain will jeopardize the proper spatial and temporal expression pattern. In addition, Benfey et al (1989, EMBO J, 8(8):2195-2202; page 2200, left column 2nd paragraph) teach that not only are the promoter domains important for specifying proper spatial and temporal expression but that when all domains were present, the quantity of expression increased.

Applicants' claims are drawn to the progeny of a transgenic plant comprising Applicants' invention. The state-of-the-art teach that operably linking a nucleic acid molecule encoding a cytotoxic product to a promoter sequence that expresses in flower primordia or in flower organ primordia that produce gametes, will be sterile and not produce progeny. Day et al (1995, Development 121:2887-2895) teach the AP3 promoter operably linked to a nucleic acid molecule encoding the diphtheria toxin A chain polypeptide transformed into plants did not produce progeny (page 2888, right column, 3rd paragraph and page 2891, left column, 1st full paragraph).

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:12 and non-disclosed fragments of the coding sequence of the *Arabidopsis* AP1 gene as probes or by designing primers to undisclosed regions of SEQ ID NO:12 and undisclosed regions of the *Arabidopsis* AP1 gene and isolating or amplifying fragments, subcloning the fragments, producing expression vectors also comprising said amplified fragments operably linked to a nucleic acid molecule encoding the diphtheria toxin A chain polypeptide and transforming plants therewith, in order to identify those, if any, that when over-expressed produce plants which produce sterile flowers.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 7-9, 10, 13-14, 18-21, 24-25, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Day et al (1995, Development 121:2887-2895).

The claims are drawn to a transgenic plant, a method of producing a transgenic plant, and an isolated nucleic acid molecule comprising a floral organ selective regulatory element, or wherein said regulatory element is an AP1 regulatory element, or wherein said AP1 regulatory element has substantially the nucleotide sequence of *Arabidopsis* AP1 promoter of SEQ ID NO:12 or an active fragment thereof. Applicants' claims are also drawn to a tissue of said transgenic plant capable of vegetative and non-vegetative propagation. The office interprets non-vegetative propagation to mean seed, or tissues which give rise to seeds. Because of the 112 2nd paragraph rejection of "AP1 regulatory element" as discussed above, the Office interprets "AP1 regulatory element" as any promoter sequence that expresses at least in part, in one or more floral organs of a plant. Applicants define "substantially the nucleotide sequence" as a floral organ selective regulatory element having nucleotide additions, deletions or substitutions relative to the AP1 promoter and retaining substantially the ability to confer selective expression in one or more floral organs (page 18, 2nd full paragraph). Given this definition, the Office interprets "substantially the nucleotide sequence" to mean any sequence that directs expression in one or more floral organs. The office interprets "an active fragment thereof" to read on one base pair. Applicants broadly define "suppressed flowering" to mean that the transgenic plants produce flowers that are completely sterile or can be characterized by reduced fertility, although

generally flowering is suppressed to the extent that the transgenic plant is completely sterile (page 7, 2nd paragraph).

Day et al disclose an isolated nucleic acid molecule comprising a 1.9 kb AP3 genomic clone operably linked to a nucleic acid sequence encoding the diphtheria toxin A chain polypeptide (page 2888, right column, 1st two paragraphs). The 1.9 kb AP3 genomic clone directs expression in the petals and stamens of an *Arabidopsis* flower, said tissues give rise to seeds (page 2889, left column, top paragraph). Day et al disclose using *Agrobacterium tumefaciens* to introduce said nucleic acid molecule into *Arabidopsis*, to produce a transgenic plant. Day et al disclose that *Arabidopsis* plants transformed with said nucleic acid molecule exhibited flowers with no petals or stamens (page 2889, paragraph bridging the left and right columns). Day et al also disclose that some of the ovules did not appear to have normal integuments (page 2890, left column, bottom paragraph) and that none of the seed recovered from a cross with wild-type pollen were viable (page 2891, left column, 1st full paragraph). Given the Office's interpretation of "AP1 regulatory element" and "substantially the nucleotide sequence" as discussed above, the disclosed nucleic acid molecule comprising the AP3 promoter, method and transgenic plant of Day et al anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3, 7-9, 10, 11-14, 18-21, 24-25, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al (1995, Development 121:2887-2895).

The claims are drawn to a transgenic plant, a method of producing a transgenic plant, and an isolated nucleic acid molecule comprising a floral organ selective regulatory element, or wherein said regulatory element is an AP1 regulatory element, or wherein said AP1 regulatory element has substantially the nucleotide sequence of *Arabidopsis* AP1 promoter of SEQ ID NO:12 or an active fragment thereof. Applicants' claims are also drawn to a tissue of said transgenic plant capable of vegetative and non-vegetative propagation, or wherein said transgenic plant is a woody plant or a tree. The claims are also drawn to a kit comprising packaging containing a floral organ selective regulatory element operatively linked to a nucleotide sequence encoding a cytotoxic gene product and instructions for transforming a susceptible plant, wherein said regulatory element is an AP1 regulatory element. The office interprets non-vegetative propagation to mean seed, or tissues which give rise to seeds. Because of the 112 2nd paragraph rejection of "AP1 regulatory element" as discussed above, the Office interprets "AP1 regulatory element" as any promoter sequence that expresses at least in part, in one or more floral organs of a plant. Applicants define "substantially the nucleotide sequence" as a floral organ selective regulatory element having nucleotide additions, deletions or substitutions relative to the AP1 promoter and retaining substantially the ability to confer selective expression in one or more floral organs (page 18, 2nd full paragraph). Given this definition, the Office interprets "substantially the nucleotide sequence" to mean any sequence that directs expression in one or more floral organs. The office interprets "an active fragment

thereof" to read on one base pair. Applicants broadly define "suppressed flowering" to mean that the transgenic plants produce flowers that are completely sterile or can be characterized by reduced fertility, although generally flowering is suppressed to the extent that the transgenic plant is completely sterile (page 7, 2nd paragraph).

The teaching of Day et al have been discussed above.

Day et al do not teach a transgenic woody plant or tree or a kit comprising instructions.

Given the recognition of those of ordinary skill in the art the value of producing a transgenic plant characterized by suppressed flowering comprising a nucleic acid molecule comprising a floral organ selective regulatory element operably linked to a nucleotide sequence encoding a cytotoxic gene product, as taught by Day et al, it would have been obvious to transform a woody plant or tree with said nucleic acid molecule because woody plants and trees also have flowers. Claims 31-33 are directed to a kit. Day et al does not teach combining printed matter with the nucleic acid molecule comprising a floral organ selective regulatory element operably linked to a nucleotide sequence encoding a cytotoxic gene product. However, it is conventional to include printed matter with reagents, i.e, a nuclei acid molecule comprising a floral organ selective regulatory element operably linked to a nucleotide sequence encoding a cytotoxic gene product, for the purpose of communicating the reagent's use to a second person. Therefore, it would have been obvious to combine the nucleic acid molecule comprising a floral organ selective regulatory element operably linked to a nucleotide sequence encoding a cytotoxic gene product with printed matter. "Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." In re Gulack, 217 USPQ 401 at 404 (CAFC 1983).

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
November 29, 2004

AMY J. NELSON, PH.D
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